

-continued

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21

<210> SEQ ID NO 16

<211> LENGTH: 27

<212> TYPE: DNA

<213> ORGANISM: Mus musculus

<400> SEQUENCE: 16

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27

What is claimed is:

1. An isolated antibody or an antigen-binding fragment thereof, which specifically binds to HER3 comprising a heavy chain variable region comprising SEQ ID NO:1, or an amino acid sequence at least 90% identical thereto, and a light chain variable region comprising SEQ ID NO:2.

2. The antibody or antigen-binding fragment of claim 1, wherein the VH comprises an amino acid sequence at least 80% identical to the amino acid sequence of SEQ ID NO: 1, and wherein the VL comprises an amino acid sequence at least 80% identical to the amino acid sequence of SEQ ID NO: 2.

3. The antibody or antigen-binding fragment of claim 1, wherein the VH comprises an amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO: 1, and wherein the VL comprises an amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO: 2.

4. The antibody or antigen-binding fragment of claim 1, wherein the VH comprises an amino acid sequence at least 95% identical to the amino acid sequence of SEQ ID NO: 1, and wherein the VL comprises an amino acid sequence at least 95% identical to the amino acid sequence of SEQ ID NO: 2.

5. The antibody or antigen-binding fragment thereof of claim 1, which comprises a VH comprising SEQ ID NO: 1 and a VL comprising SEQ ID NO: 2.

6. The method of claim 1, wherein the antibody comprises a heavy chain variable domain comprising SEQ ID NO: 1.

7. The method of claim 1, wherein the antibody comprises a light chain variable domain sequence comprising SEQ ID NO: 2.

8. A nucleic acid molecule comprising a first nucleotide sequence that encodes a heavy chain variable region (VH), or a second nucleotide sequence that encodes a light chain variable region (VL), or both, of an antibody molecule capable of binding to human HER3, wherein the antibody molecule comprises: (a) a VH comprising a VH CDR1 amino acid sequence of SEQ ID NO: 3; a VH CDR2 amino acid sequence of SEQ ID NO: 4, and a VH CDR3 amino acid sequence of SEQ ID NO: 5; and a VL comprising a VL CDR1 amino acid sequence of SEQ ID NO: 6, a VL CDR2 amino acid sequence of SEQ ID NO: 7, and a VL CDR3 amino acid sequence of SEQ ID NO: 8.

9. An expression vector comprising the nucleic acid molecule of claim 8.

10. An isolated host cell comprising the nucleic acid molecule of claim 8.

11. A method of producing an antibody molecule or fragment thereof, comprising culturing the host cell of claim 8 under conditions suitable for gene expression, wherein said host cell comprises said first nucleotide sequence that encodes a VH and said second nucleotide sequence that encodes a VL.

12. The nucleic acid molecule of claim 8, wherein the first nucleotide sequence encodes a VH comprising the amino acid sequence of SEQ ID NO: 1; and/or wherein the second nucleotide sequence encodes a VL comprising the amino acid sequence of SEQ ID NO: 2.

13. An isolated nucleic acid comprising a sequence encoding the antibody or antigen-binding fragment according to claim 1.

14. An isolated nucleic acid comprising a sequence encoding at least the heavy chain and the light chain of the antibody according to claim 1.

15. The antibody or antigen-binding fragment of claim 1, wherein the antibody is a monoclonal antibody, human antibody, a humanized antibody, a chimeric antibody, a recombinant antibody, a multispecific antibody, or an antigen-binding fragment thereof; wherein the antigen-binding fragment is an Fv, Fab, F(ab')₂, Fab', dsFv, scFv, or sc(Fv)₂; or a diabody, ScFv, SMIP, single chain antibody, affibody, avimer, nanobody or a single domain antibody wherein the antibody or antigen-binding fragment thereof is conjugated to at least one heterologous agent.

16. The antibody or antigen-binding fragment of claim 1, wherein the antibody is a monoclonal antibody.

17. The antibody according to claim 1, wherein the antibody isotype is selected from the group consisting of an IgG1, an IgG2, an IgG3, an IgG4, an IgM, an IgA1, an IgA2, an IgAsec, an IgD, and an IgE antibody.

18. The anti-HER3 antibody of claim 1, wherein the antibody is an IgG2 isotype.

19. The antibody molecule of claim 1, which comprises a light chain constant region of kappa or lambda.

20. A method for treating a subject having a HER3-expressing cancer comprising administering an effective amount of an antibody of claim 1 to the subject.

21. The method of claim 20, wherein the subject is human.

22. The method of claim 20, wherein the subject is a human and the cancer is selected from the group consisting of is a breast cancer, lung cancer, head & neck cancer, skin cancer, prostate cancer, esophageal cancer, tracheal cancer, skin cancer brain cancer, liver cancer, bladder cancer, stomach cancer, pancreatic cancer, ovarian cancer, uterine cancer, cervical cancer, testicular cancer, colon cancer, colorectal cancer or skin cancer. multiple myeloma, gastric cancer,